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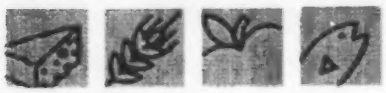
Food Safety Assessment Program

Assessment Report of the Canadian Food Inspection Agency Activities Related to the Safety of Aquaculture Products



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Rapport d'évaluation des activités de l'Agence canadienne d'inspection des aliments reliées à la salubrité des produits aquicoles

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Executive Summary

In April 1997 the *Canadian Food Inspection Agency Act* established the Canadian Food Inspection Agency (CFIA), reporting to the Minister of Agriculture and Agri-food. Health Canada is responsible for assessing the effectiveness of the Agency's activities related to food safety. The objective of this assessment was to determine the effectiveness of CFIA activities related to the safety of domestic and imported aquaculture products. We examined inspection, laboratory and policy development activities relating to domestic and imported aquaculture products. We also examined the activities of the Feed Program related to aquaculture products. The roles and responsibilities of the various partners involved were also examined, as aquaculture is clearly an area of shared jurisdictions. We assessed the Agency programs in place and food safety activities which took place between April 1, 1997 and March 31, 2000.

Key Observations

Aquaculture is one of Canada's fastest growing industries. While wild fish stocks in Canada and in several other countries continue to suffer a significant collapse, Canadians and people worldwide continue to need a reliable supply of fish. The value of aquaculture in Canada has increased steadily from $7 million in 1984 to $558 million in 1999 representing a production of over 113,000 tonnes and about 30% of the total landed value of the Canadian fisheries sector.

CFIA is addressing these challenges by undertaking an array of activities covering aquaculture products. The presence of veterinary drug residues represents an important key potential hazard in aquaculture products. The Agency has put in place the Quality Management Program (QMP), an inspection program for fish based on Hazard Analysis Critical Control Point (HACCP) principles. Tests for drugs are conducted regularly on these products as part of a verification of the QMP. Compliance with administrative maximum residue limits is high for the drugs that were tested. Furthermore, there is a satisfactory follow-up to investigate root-causes in cases of non-compliance.

These activities, however, can be improved. For example, the testing for drugs could be more reliable if they were to better reflect the prescription pattern. Based on our analysis of prescriptions, 66% of all drugs prescribed were covered by CFIA's test and 34% were not tested for. On the other hand, 69% of these tests were conducted for drugs widely prescribed by the industry and 31% for drugs used only on a limited basis.

Feeds constitute a strategic element of the food chain. It is especially important for aquaculture since most drugs prescribed to aquaculture fish are administered through their feed. The Agency inspects feeds continuously. However, its inspection activities pertaining to aquaculture feeds could be more effective if they covered all species and all drugs prescribed, and if the Agency followed-up more rigorously on cases of non-compliance especially those related to excessive levels of drugs in feed. Some of these issues will be addressed in new regulations for medicated feeds that have been proposed by CFIA.

The assessment also examined the use of service standards by the Agency. Service standards constitute a good tool for defining the level of service clients can expect. Standards also enable the organization to keep track of its performance. We found that CFIA has begun to set up the conceptual and practical basis for the implementation of service standards, however improvements could be made in their formulation and in the manner by which they are tracked and monitored.

Jurisdiction for aquaculture is shared between CFIA and its provincial and territorial counterparts. The CFIA has repeatedly stated that its goal is to improve inter-governmental co-operation by both reducing overlap and duplication, and streamlining service delivery. Agreements with provincial governments that could lead to fewer gaps and less duplication in inspection activities were in place before the Agency was created. However, to date the information exchanged between the parties has been minimal. It is expected that new agreements that are being negotiated will lead to better exchange of information. The Agency also co-operates fruitfully with other federal departments and the industry.

Conclusion

In summary, the Canadian Food Inspection Agency is conducting an array of activities to monitor the safety of aquaculture products. It could increase the effectiveness of its food safety programs related to aquaculture products by improving the access to and use of information pertaining to aquaculture products that is often already available or could be obtained with minimal efforts.

Introduction

Aquaculture is a Fast Growing Industry

1 Aquaculture is one of Canada's fastest growing industries. While wild fish stocks in Canada and in several other countries continue to suffer a significant collapse, Canadians and people worldwide continue to need a reliable supply of fish. Driven by this need to fill the gap and through technological innovations, better husbandry practices and constantly evolving methods, aquaculture's contribution to the food supply is now growing at a rapid rate.

2 Aquaculture is a relatively new and rapidly growing activity in various parts of the world and definitions abound. For the purpose of this assessment we will retain the universally accepted definition of aquaculture, adopted by the Food and Agriculture Organisation of the United Nations (FAO). According to this definition, aquaculture is "the culture of aquatic organisms including fish, molluscs, crustaceans and aquatic plants. Culture implies some form of intervention in the rearing process to enhance production, such as regular stocking, feeding, protection from predators, etc. Culture also implies individual or corporate ownership of the stock being cultivated." For finfish, aquaculture is analogous to the livestock and poultry industries - animals are raised in captivity and then slaughtered and sold.

3 The value of aquaculture in Canada has increased steadily from $7 million in 1984 to $558 million in 1999 representing a production of over 113,000 tonnes and about 30% of the total landed value of the Canadian fisheries sector. Worldwide, the value of aquaculture increased from $11.9 billion (U.S.) to $42 billion (U.S.) during the same period.

4 There are 600 identified aquaculture producers in Canada. The total estimated direct employment figures on a national basis within the aquaculture industry are in excess of 5,000 workers. It is therefore not surprising to observe that aquaculture has captured the attention of various levels of government. The Federal Aquaculture Development Strategy announced in 1995 established the general framework and direction for aquaculture and, in 1998, Canada appointed its first Commissioner for Aquaculture Development. The Commissioner's mandate is to bring together all appropriate federal government resources, lead required regulatory reforms and work with the provinces to develop the aquaculture industry. The Commissioner is responsible for implementing the 1995 Federal Aquaculture Development Strategy.

Legislation and Roles and Responsibilities Relating to Aquaculture

5 At the federal level, a number of departments are involved in aquaculture-related activities. The Department of Fisheries and Oceans (DFO) conducts research and has various regulatory responsibilities regarding fish habitat, fish health, etc. Environment Canada administers a number of regulations that affect aquaculture. It is also responsible for monitoring water quality (under the Canadian Shellfish Sanitation Program). Health Canada sets guidelines for bacteria, chemicals and toxins in food products and is responsible for approving veterinary drugs used in aquaculture. Pest control products which could affect aquaculture are regulated by the Pest Management Regulatory Agency (PMRA) of Health Canada under the *Pest Control Products Act* (PCPA) and the *Food and Drugs Act* (FDA).

6 The Canadian Food Inspection Agency (CFIA)'s responsibilities, with respect to aquaculture, which will be examined more closely in this assessment, are derived from the *Fish Inspection Act* (FIA) and the *Food and Drugs Act (FDA)*. The *Fish Inspection Act* governs the inspection of fish for international and inter-provincial trade. It sets out the federal role in ensuring that fish and seafood meet strict national quality standards from the time they leave the water to the time they are distributed to the marketplace for inter-provincial trade or export to other countries. The Fish Inspection Regulations made pursuant to the Act, require that all fish intended for export must be processed in an establishment where a Quality Management Program is in place. The FDA applies equally to all food whether traded inter or intra-provincially and states that "No person shall sell an article of food that is adulterated." In particular Division 15 of the Regulations which pertains to veterinary drugs is relevant to aquaculture.

7 The Agency, through the *Feeds Act*, also regulates the manufacture, import and sale of all livestock feeds. It performs tasks such as review and monitoring of feed medication levels, usage, direction for use and drug withdrawal times as well as product label; registers certain categories of feed; and undertakes toxicological assessments of new feed ingredient. CFIA is also responsible for regulating the manufacture, importation and sale of veterinary biologics used to treat fish in aquaculture installations under the *Health of Animals Act*. The Feed Program also undertakes reviews of previously approved feeds and feed ingredients if new information comes to light that there may be safety or performance concerns associated with the product (e.g. survey of clays and fish oils for dioxin/PCB contamination).

8 Under their own regulations, the provinces inspect fish processing plants that carry out intra-provincial trade and have Memoranda of Understanding with the Agency covering their respective responsibilities. Relevant activities performed by the provinces include approval and monitoring of cages sites and the regulation of the use of pesticides. Some provinces also enforce and monitor standards established under the *Fisheries Act* to ensure that pesticides do not adversely affect the habitat or native fish stocks in any way. Some provinces also monitor hatcheries and aquaculture operations.

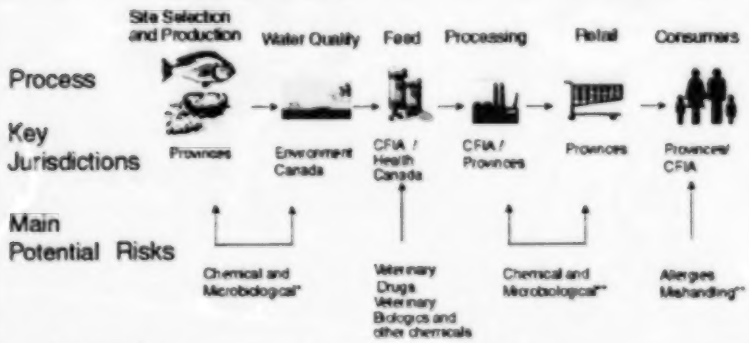
Key Risks Associated with Aquaculture

9 From a food safety perspective, aquaculture products, like any other food, are associated with potential risks to the consumers. These risks are microbiological and chemical. We have conducted an extensive review of the scientific literature to identify the potential risks associated with aquaculture. The main microbiological risks are usually associated with molluscs, since both wild and cultivated varieties could be exposed to human pathogens and viruses.

10 Environmental chemical contaminants and pesticides which may be found in aquaculture fish and molluscs also pose a potential human health hazard. For example, residues of various substances may accumulate in fish harvested from waters that contain varying amounts of industrial chemicals, pesticides, and toxic material. These levels of accumulation may potentially cause illness in humans. Pesticides used to treat fish may also be a concern. Finally residues of antimicrobial drugs used on certain aquaculture fish stocks, may be present in tissues of fish sold as food. While there are health benefits to treated animals associated with use of antimicrobials, drug residues may also pose health risks related to the inherent toxicity of the drug and the potential to cause allergies and contribute to the development of antimicrobial resistance in humans. CFIA is participating with Health Canada in a study on the prevalence of antimicrobial resistant bacteria in marine finfish aquaculture sites in British Columbia.

11 The various connections between aquaculture and the food safety continuum as well as the related roles of the key jurisdictions are summarized graphically in Exhibit 1.

Exhibit 1
Aquaculture Continuum



Source: Health Canada, Bureau of Food Safety Assessment, 2000

Objective and Scope

12 The objective of this assessment was to determine the effectiveness of the Agency activities related to the safety of domestic and imported aquaculture products. This assessment focussed on CFIA's activities pertaining to the safety of aquaculture products. We examined inspection, laboratory and policy development activities relating to domestic and imported aquaculture products. As the toxicological hazards posed by marine biotoxins in shellfish harvested in Canada (including aquaculture products) were addressed in 1997, in a Health Canada audit of the Canadian Shellfish Sanitation Program, they were not covered in this assessment. We also examined the activities of the feed program related to aquaculture products. The roles and responsibilities of the various partners involved were also examined, as aquaculture is clearly an area of shared jurisdictions. We assessed the Agency programs in place and food safety activities which took place after April 1, 1997, the date of the formation of the Agency.

13 The assessment was conducted at the CFIA Headquarters and in the Operational Areas of Atlantic, Ontario and Western. We visited Agency's area and regional offices and six privately owned and operated feed mills. The examination phase included activities such as: review and analysis of program plans, procedures and manuals, inspection and compliance reports, minutes of meetings, memoranda of agreements, internal studies, performance reports, documents on fish diseases and their treatments, collection and analysis of prescriptions, laboratory methodology, industry statistics, etc. Interviews with key Agency operation and program staff and stakeholders were also conducted. For more information on this assessment, refer to the *About the Assessment* section at the end of the report.

Observations and Recommendations

I. Inspection Activities Related to Aquaculture Food Products

14 Aquaculture has grown rapidly in recent years and now encompasses a variety of products. The presence of veterinary drug residues represents a key potential hazard in aquaculture products. The Agency has put in place the Quality Management Program (QMP), an inspection program for fish based on Hazard Analysis Critical Control Point (HACCP) principles. Tests for drugs are conducted regularly on these products as part of a verification of the QMP, however, their results could be more reliable if they more accurately reflected the prescription pattern. Compliance with administrative maximum residue limits is high for the drugs that were tested. Furthermore, we found that there is a satisfactory follow-up to address cases of non-compliance.

A. Planning of Inspection Activities Related to Aquaculture Products

Planning has improved but more progress needs to be done

15 Proper planning of food inspection activities is important because it enables resources to be targeted to areas where the real and potential risks are expected to occur. Since the Agency was created (April 1, 1997), not all Areas have prepared work plans on an annual basis. In 1997-98, all three areas visited during the assessment (Atlantic, Ontario and Western) prepared work plans. However, in 1998-99, no formal work plans were prepared in either Atlantic or Ontario Areas. Agency officials told us that these Areas had used the work plans from the previous year. According to these officials this was done because of the transition period following the creation of the Agency. However, they indicated that the 1997-98 work plans were put through a validation process. We were not able to establish if this validation has taken place. A formal Annual Review at the Regional level was done by Pacific Region (now part of the Western Area) for fiscal year 1997-98. The only reference to aquaculture activities was the number of analyses conducted for drug residues compared to the number of analyses planned (1997/98 Pacific Region report).

16 At the beginning of 1999, the CFIA developed a new and integrated approach to planning and reporting. This approach is described in the *Planning and Reporting Framework and Process, 1999-2000*. It includes a proposed planning and reporting cycle, roles and responsibilities and reporting and monitoring mechanisms.

17 According to the Framework, the Operations Branch of the Agency has primary responsibility for delivering the inspection programs according to the approved work plans. Operations work plans are prepared at the regional (area) level and contain the following information: consolidated inspection requirements for each region (area) provided by the CFIA Programs, workload indicators (e.g., the number of samples, operations, inspections, etc.), planned outputs and, planned resource utilization. The Agency also indicates in the Framework that it will measure actual vs. expected performance to determine the extent to which it has achieved its planned results. The Agency will present this information in annual reports.

18 For fiscal year 1999-2000 work plans were produced for three Atlantic provinces and British Columbia. Despite the Framework's good intentions, we note that in the planning documents for fiscal year 1999-2000, there still are few references to workload indicators, except FTE allocation. At the time of this assessment, there was no formal tracking of actual vs. planned performance or formal quarterly review report available at the area level. National roll-ups are expected to be prepared after the end of the fiscal year. We also note that planning documents for fiscal year 1999-2000 make only minimal references to aquaculture products. This is a concern since aquaculture represents almost a third of the total landed value of the commodities covered by the Fish Program.

Recommendation

The CFIA should track the implementation of its working plans both at the area and the national levels.

Agency Response

As noted in this report, the CFIA has recently designed and implemented a formal quarterly review process as part of its overall planning and reporting cycle. This process is designed to track the implementation of working plans and to provide performance information. The objectives of this process are to review and analyse the accomplishments and challenges in delivering each of CFIA's 14 program areas and to identify any actions necessary to address the challenges.

Recommendation

The CFIA should take into consideration the aquaculture sector in its planning for inspections and sampling activities of the Fish Program.

Agency Response

The CFIA does take into consideration the aquaculture sector when designing programs and planning inspection and sampling activities. Under the Quality Management Program (QMP) requirements of the Fish Inspection Regulations federally-registered establishments are required to identify that they are processing aquaculture products. They are also required to identify any potential hazards associated with aquaculture products, implement controls to address the hazards and develop a mechanism for trace back in the event of a problem. The CFIA, when evaluating the implementation of the establishment's QMP plans, will confirm that the appropriate controls are in place for all hazards.

With respect to imported aquaculture products, relatively few species (e.g. Asian and South American shrimp, all imported Atlantic salmon, rainbow trout, Tilapia and catfish) are currently imported. These products are targeted under CFIA's import inspection program for drug residue testing. This ensures that drug residue testing will be carried out wherever there is a potential that fish have been treated with therapeutants.

B. Tests Conducted and Follow-ups of Results

19 The presence of veterinary drugs residues represents a key potential hazard in finfish aquaculture products. The CFIA has put in place the Quality Management Program (QMP), an inspection program for fish based on Hazard Analysis Critical Control Point (HACCP) principles. QMP is the main control system used by CFIA to monitor the safety and quality of fish and seafood. The Agency regularly tests for the presence of drugs in aquaculture products as part of a verification of the QMP. However, these tests could be more effective if they would take into account the actual pattern of drugs used.

The CFIA has put in place the Quality Management Program

20 Although, the aquaculture industry has made considerable progress to create favourable growing environments, infectious diseases remain an inherent aspect of fish farming. Stress to fish resulting from poor farming practices by some aquaculture producers will continue to increase susceptibility to infections that may dictate the use of antimicrobial drugs. The use of these drugs by the aquaculture industry is far from being intensive based on the fact that a very small proportion of all manufactured feed is medicated and that preventative use of drugs is a rare occurence. Excess residues could still be found, if label instructions for each drug are not properly followed. The label contains species-specific information such as dosage, reason for treatment and the withdrawal period. (This is the time required for the fish to metabolize the drug to a level that poses no harm to consumers).

21 The Veterinary Drugs Program (VDP) (formerly the Bureau of Veterinary Drugs) of Health Canada is responsible for approving drugs used by the aquaculture industry. Seven therapeutic products have been approved for use in Canada so far (see Exhibit 2). Most of these drugs can be obtained only through a prescription provided by a veterinarian. The exception is Terramycin-Aqua® (oxytetracycline), which can be obtained in certain dosage "over the counter" (i.e., without a prescription). Health Canada also issues, on a case by case basis, temporary authorizations to use drugs not approved in Canada through various mechanisms referred to as Emergency Drug Releases and Experimental Studies Certificates. Finally, veterinarians can take the responsibility for issuing prescriptions for drugs authorized for animals other than fish, a practice sometimes referred to as "off-label" prescriptions.

Exhibit 2
List of Therapeutic Products Approved by Health Canada for Use in Canada

Therapeutic Product Brand Names	Active Ingredients	Date of Notice of Compliance	Species	Technical Use	Administrative Maximum Residue Limits (AMRL)
Romet 30 (Hoffman-LaRoche)	Sulphadimethoxine Ormetoprim	27 August 1990	Salmonids	Antimicrobial	0.1 ppm *
Tribrissen 40 (Coopers Agropharm)	Sulphadiazine Trimethoprim	20 October 1992	Salmonids	Antimicrobial	0.1 ppm 0.1 ppm
Terramycin-Aqua (Pfizer Inc.)	Oxytetracycline	7 July 1989	Salmonids Lobster	Antimicrobial	0.1 ppm
Aquaflor (Schering-Plough)	Florfenicol	3 April 1996	Salmonids	Antimicrobial	0.8 ppm
Aqua Life-TMS (Syndel Labs)	Tricaine-methanesulfonate	19 May 1995	Salmonids	Anaesthetic	*
Parasite-S (Western Chemicals)	Formaldehyde	18 July 1994	Salmonids	Antifungal	Not Needed
Perox-Aid (EKA Chemicals)	Hydrogen Peroxide	18 September 1998	Salmonid Eggs	Antifungal	Not Needed

* No AMRL established

Source: Health Canada, Bureau of Veterinary Drugs, 2000

22 The CFIA has put in place the Quality Management Program (QMP), an inspection program for fish based on Hazard Analysis Critical Control Point (HACCP) principles. The Fish Inspection Regulations made pursuant to the *Act* state that all fish intended for export must be processed in an establishment where a QMP is in place. Since the creation of the Agency in April 1997, an initiative to re-engineer QMP has been undertaken. The time period covered by our assessment has therefore been one of transition for the QMP model. For risks associated with aquaculture, i.e., the presence of drug residues, the processing establishments are required to identify the presence of drug residues as a potential hazard and implement effective controls. The Agency provides a guideline document which lists some of the possible controls an establishment may choose from. For instance, among other options, the establishment could require a supplier certification of proper on-farm drug usage to accompany each lot as part of a critical control point within a HACCP plan or they could conduct their own periodic analytical testing to verify the effectiveness of the control procedures. The inspectors will use this guideline document to aid in assessing the establishment's documented controls when conducting the systems verification.

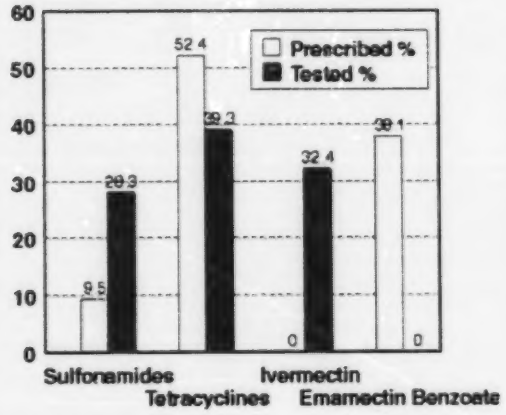
23 The QMP, as a HACCP-based program, relies on a number of possible sources of information to determine the safety of the systems, such as laboratory tests, documentation provided by producers, certification programs implemented by the industry, third-party verification, audits of systems and procedures, etc. In particular, laboratory tests, according to basic literature on HACCP, are fundamental elements of the information necessary to ascertain the effectiveness of the systems. Because tests are science-based and constitute objective evidence, they provide useful and reliable information on the effectiveness of HACCP-based inspection programs. Tests are conducted on an on-going basis by CFIA to verify QMP.

The CFIA could use better information to evaluate the risks related to drugs

24 For the purpose of this assessment, we focussed on the testing of drug residues in aquaculture products and more specifically on drugs administered via the feed (the main method used by aquaculture producers). Taking advantage of the *Feeds Act and Regulations* requirements for feed mills to maintain, at their manufacturing sites, copies of the prescriptions, we compiled prescription records in order to develop an overview of actual drug use by the industry. In the Western Area, we obtained a total of 963 prescriptions for medicated fish feed from two feed mills for the years 1997, 1998 and 1999. For the same years in the Atlantic Area, we obtained a total of 764 prescriptions for medicated fish feed from four feed mills. In total we obtained 1,727 prescriptions for medicated fish feed from six feed mills. The vast majority of these prescriptions were for salmon. The Agency indicates that in 1998 in the Atlantic Area, 4% of all manufactured fish feed, representing approximately 3,600 metric tons, was medicated. These prescriptions account for medications in approximately 85% of medicated fish feed produced, according to information provided by the Agency.

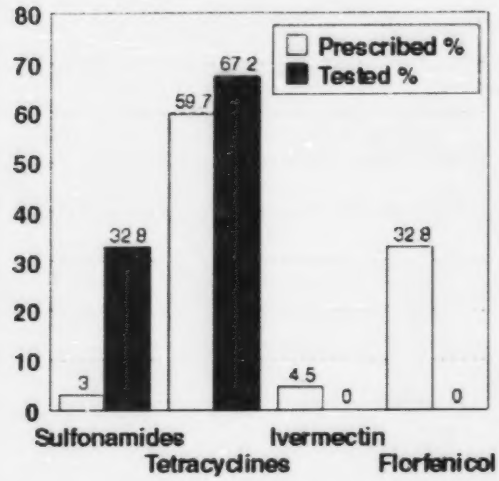
25 We used the information on prescriptions to compare the patterns of the use of drugs by aquaculture producers with patterns of testing done by CFIA. When the tests are planned, the prescriptions have generally not been issued and achieving an exact correspondance between the tests and the prescriptions is unlikely. However, an approximate match of the tests with the prescription pattern could reasonably be expected. In order to do that comparison, we focussed on the prescriptions for salmon of one kg and more, which at this weight, are more likely to be marketed (and therefore consumed) sooner after the drug treatment. We focussed on testing conducted by the Agency for QMP compliance verification. Exhibits 3 and 4 present the results of our comparison of the patterns of drugs prescribed against CFIA's testing patterns.

Exhibit 3
Comparison of Aquaculture Drugs Prescribed and Testing Patterns
(Salmon [>1 kg] – Atlantic Area – 1999)



Source: Based on prescriptions provided by the CFIA and compiled by the BFSA, 2000

Exhibit 4
Comparison of Aquaculture Drugs Prescribed and Testing Patterns
(Salmon [>1 kg] – Western Area – 1999)



Source: Based on prescriptions provided by the CFIA and compiled by the BFSA, 2000

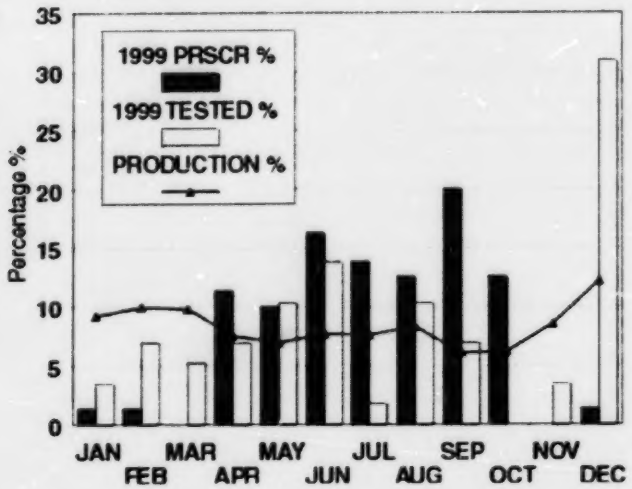
26 In the Atlantic Area, the results of our comparison indicate that the Agency focuses more effort on testing for sulfonamides drugs (Romet 30 and Tribrissen 40) and Ivermectin, than the evidence on the observed usage of these drugs would warrant. We also note that the Agency did no testing for Emamectin Benzoate, a drug recently introduced in the market, and which represents 38% of prescriptions in this Area. Emamectin Benzoate was released by Health Canada under a temporary authorisation but it had not provided this information or provided an analytical methodology to the Agency. We note that although CFIA did not request this information from Health Canada, it was aware that treatments with Emamectin Benzoate were taking place. For Tetracyclines antimicrobials, the level of testing did correspond to the drugs prescribed. We note that Oxytetracycline is also available without prescriptions at specific levels of concentration as specified in the Compendium of Medicated Ingredients Brochure (CMIB). There is therefore no readily available source of information that would allow to make an accurate estimate of the real overall drug usage for this drug that would take into account over the counter and on farm made medicated feed.

27 In the Western Area, our comparison indicates that the level of testing for Tetracyclines and Ivermectin was appropriate. Also, as was true in the Atlantic Area, the Agency spent more efforts on testing for sulfonamides antimicrobials than the number of prescriptions issued for this drug would warrant. By contrast the Agency did no testing at all for Florfenicol, a drug that represents 33% of prescriptions in the Western Area. The case of Emamectin Benzoate and Florfenicol is discussed in paragraph 50.

28 Since the prescriptions are dated, we were also able to use this information to assess the timeliness of the tests conducted. We used this information to compare variations of proportion of workload handled on a monthly basis for the testing of Oxytetracycline a drug used both in the Atlantic and the Western Areas. Since the tests are conducted on fish that have been sent for processing we also took into account, the level of production for each month. The results are presented in Exhibit 5 and 6 for the Atlantic and the Western Areas, respectively. Because of the length of the withdrawal period for some of these drugs, it is always possible that residues will be present months after the treatment. However since the levels of residues are higher when the treatment is more recent it would be desirable to adjust the level of testing to the monthly prescription pattern to capture more recent treatments which pose the higher risks to heath in case they would be processed prematurely.

29 The results in Exhibit 5 and 6 show that in the Atlantic Area, the drugs are not always tested when they are more likely of being detected at a critical level. For instance in July and October, where many prescriptions are issued very few tests are conducted. We also note that the level of effort to conduct tests in December is higher than necessary considering the level of prescriptions issued during this month. We found that the variations in the level of production did not explain this discrepancy (i.e., production was relatively constant given the variations in prescription patterns). In the Western Area we found a greater consistency between the distribution of testing efforts and the level of prescriptions throughout the year although we note that in some months few tests are conducted compared to the number of prescriptions issued and the level of production observed.

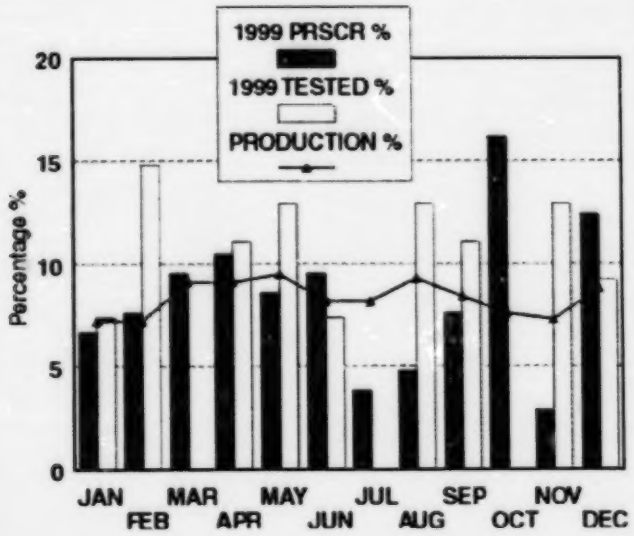
Exhibit 5
Monthly Variation of Drug Prescribed, Testing Patterns and Finfish Production (Atlantic Area) 1999



Source: Based on prescriptions provided by the CFIA and compiled by the BFSA, 2000

Note: Production data provided by the Department of Fisheries and Oceans is only broken down by month for exports of farmed products. Because exportations represent 70% of production in Canada, we consider it a good indication of the overall production level.

Exhibit 6
Monthly Variation of Drug Prescribed, Testing Patterns and Finfish Production (Western Area) 1999



Source: Based on prescriptions provided by the CFIA and compiled by the BFSA, 2000

Note: Production data provided by the Department of Fisheries and Oceans is only broken down by month for exports of farmed products. Because exportations represent 70% of production in Canada, we consider it a good indication of the overall production level.

30 In summary our analysis shows that there are discrepencies between drug prescription patterns and the focus of testing. In 1999, 66% of all drugs prescribed were covered by CFIA's test and 34% were not tested for. On the other hand, 69% of these tests were conducted for drugs widely prescribed by the industry and 31% for drugs used only on a limited basis. By using existing information available, such as the prescriptions that could be obtained through its Feeds Program or by employing information on the temporary authorizations for drugs issued by Health Canada mentioned in paragraph 21, CFIA could re-allocate its resources and testing efforts in a way that would result in a more effective targeting of the analyses conducted. This information could also be shared with the processing establishments to enhance the quality and relevance of their own testing efforts.

Recommendation

CFIA should use the available sources of information (field intelligence, temporary authorizations issued by Health Canada and prescriptions) to identify the drugs that should be tested in domestic aquaculture products and to determine the timing of the tests.

Agency Response

The CFIA supports and encourages the timely exchange of information on therapeutant use in aquaculture. To address this issue, CFIA has invited departments (Department of Fisheries and Oceans, Health Canada, Environment Canada) to participate in an Interdepartmental Committee on Therapeutant Use in Aquaculture (ICTUA). The first ICTUA was held on 16 May, 2001. The committee provides a forum for departments to share specific information on temporary drug authorizations and to share knowledge on therapeutant use in aquaculture and off-label veterinary prescriptions.

CFIA will continue to use available sources of information to identify the drugs that should be monitored in domestic aquaculture products. Sampling frequency and timing will continue to be directed by the Quality Management Program compliance verification activities.

31 We also reviewed the tests performed to detect drug residues in imported aquaculture fish. We did not have access to detailed information on actual prescriptions as we did for domestically produced aquaculture products. Given this situation, we reviewed the scientific and trade literature to determine which drugs are used in countries exporting aquaculture products. We then compared that information against the types of tests that the CFIA carries out on imported aquaculture products. We observed that most of the tests done by the Agency are for drugs approved in Canada, i.e. sulfonamides and tetracyclines (83% of the tests conducted in the Atlantic Area, 83% in the Western Area and 99% in the Ontario Area). Although many other countries also use these drugs, we note the Agency rarely tests for many classes of antimicrobials (such as quinolones and nitrofurans) that have been reported as being used on fish in countries exporting to Canada. These antimicrobials present risks similar to other antimicrobials.

Recommendation

CFIA should expand the spectrum of drugs that are tested for imported aquaculture products in order to include classes of drugs also used in other countries by aquaculture producers.

Agency Response

The CFIA has established government to government agreements with countries that export aquaculture products; examples include Thailand , Indonesia and Ecuador. These country to country agreements prescribe foreign government controls and processes to ensure exported products meet Canadian requirements, including the use of approved drugs and the absence of drug residues in products exported to Canada. The CFIA audits these agreements to ensure government obligations are appropriately met. The CFIA will continue to work with foreign countries under its agreements, as well as utilizing all available intelligence to target imported aquaculture products for appropriate analyses both within the existing agreements, and with products coming from non-agreement countries.

32 According to the Food and Agriculture Organization of the United Nations (FAO), more than 250 aquaculture species were reported world-wide in 1995. In the case of imported products, CFIA, in order to ensure an appropriate coverage of aquaculture species imported in Canada, makes conservative assumptions regarding which products are aquacultured. For instance it assumes that all shrimps are aquaculture products even though some of them may be wild products. However, it does not have any estimates of the respective proportion of aquaculture and wild products. Since the Agency targets 5% of imported shipments to be tested for veterinary drugs, this absence of knowledge of the proportion of imported products that are aquacultured, limits the capacity of the CFIA to estimate the bias of this inclusion of wild products in tests of veterinary drugs (i.e., wild products will always be negative). This means that the Agency could not know with a sufficient level of statistical certainty that its target of 5% is representative of imported shipments to be tested for veterinary drugs. CFIA officials indicated that inspectors do verify with the importers if the products are aquacultured. However, this procedure is not documented and we could not confirm if it is taking place.

Recommendation

CFIA should use the available sources of information in order to verify that its samples are representative of imported aquaculture products treated with veterinary drugs.

Agency Response

The CFIA will use all available sources of information, such as information provided through foreign government regulatory authorities where the CFIA has fish inspection agreements and through the Food and Agriculture Organization of the United Nations (FAO), to verify that sampling plans appropriately target aquacultured products treated with therapeutants.

CFIA conducts a considerable number of tests

33 The vast majority of the tests done by the Agency indicate that aquaculture products are compliant for the drugs that were tested. In 1999, the Agency carried out 2,175 tests for drug residues for inspection purposes. Seven tests indicated that the product contained drugs above the administrative maximum residue limit (AMRL). These figures suggest a compliance rate of 99.7% for the drugs that were tested. However, these results should be interpreted with care, based on our findings, presented above. In the following sections we examine the actions taken by CFIA when drugs residues are detected.

34 In order to determine if a product is safe for consumption, chemical substances must not exceed a certain level referred to as a Maximum Residue Limit (MRL). For instance MRLs for veterinary drugs are listed in Table III of Division 15 of the Food and Drugs Regulations. Since updating this Table could be a lengthy process, Health Canada also normally establishes Administrative Maximum Residue Limits (AMRL). Health Canada considers that they adequately protect the health of Canadians. At the time of conducting this assessment, most of the antimicrobial drugs listed in Exhibit 2 were monitored with AMRLs. Improvements are underway in the Health Canada's processes for approval and dissemination of AMRLs. An update of Table III is reaching the final stages of approval. It will include three of the seven therapeutic products used in aquaculture.

The CFIA investigated the root cause when aquacultured products had non-compliant levels of drug residues

35 As noted earlier for domestic products, drug usage and drug residues are monitored through certification, routine sampling programs and QMP. Testing for drug residues in imported products with a good history of compliance are inspected for drug residues at a frequency of 5%. All shipments of imported fish from an establishment that has not been inspected in the last two years are inspected and if the shipment includes products that may have been farmed, analysis for drugs is performed.

36 From April 1997 to December 1999, 16 samples of domestic aquacultured products were found to be non-compliant for drug residues. We reviewed eight cases of domestic fish that CFIA had identified as being produced in aquaculture facilities. These cases had levels of Oxytetracycline, an antimicrobial, exceeding the established Administrative Maximum Residue Limit (AMRL) of 0.1 ppm set by Health Canada. The levels of antimicrobial in the cases reviewed ranged from 0.14 to 0.5 ppm. We noted that in the vast majority of the cases, the root cause had been investigated in order to prevent the problem from recurring. However, we found some inconsistencies in the actions taken for similar levels of antimicrobial detected. Recalls were carried out in two of the eight cases. For two of the eight cases, the product was not distributed at the retail level. For three cases involving similar levels of detected drugs, no recall was initiated, although follow-up actions were undertaken. Finally, in one case we were unable to obtain information on what action the CFIA had taken.

37 According to our review of the domestic cases, it is not clear what criteria the Agency used to decide what corrective action to take. In one case, we found documentation indicating that the Agency had been relying on a Health Risk Assessment (HRA) done by Health Canada in 1994 and was using it as a precedent to decide that 0.2 ppm of Oxytetracycline did not represent a health risk. The Agency relied on this HRA even though the established Administrative MRL of Health Canada is 0.1 ppm. This practice is consistent with a CFIA policy to not go to Health Canada for a risk assessment except in the case of new drugs or excessively high levels being detected. Since HRAs are always prepared for specific cases, we are concerned that the general use of HRAs may lead the Agency to arbitrarily redefine what constitutes an actionable MRL level.

38 From April 1997 to December 1999, eleven other samples of imported aquacultured products were found to contain non-compliant levels of drug residues. We reviewed nine of these. In the majority of the cases, CFIA gave instructions to put the foreign packers or processors on the Import Alert List. This means that, according to the Agency's procedures, all subsequent incoming shipments of products on this list would be subject to mandatory inspection until four consecutive shipments could pass the import inspection requirements. However, we found inconsistencies in the actions taken in the nine cases that we reviewed. Entry into Canada was refused for four shipments with non compliant levels of antimicrobials while in four other cases, for shipments containing similar levels of antimicrobials, no detention or recall was initiated. We noted that in two of these cases where no detention or recall was initiated, the delay to obtain laboratory results ranged from one to two months and the action taken was to detain and inspect future shipments as per the Fish Inspection Regulations. Recalls were initiated at the first point of sale for two shipments with non permitted drug residues or non compliant levels of permitted drug residues.

39 The inconsistencies in the recall decision also appear to stem from the CFIA's sampling and detention procedures and the prescribed action to be taken when excess levels of drug residues are found. According to the Agency's procedure manual : "Lots for testing for therapeutic drug residues will not normally be detained." In all cases processors or importers are informed of any problem and are required to correct it. Only when a second lot is found to exceed administrative MRLs are recalls, disposition of shipments, etc. usually carried out. We note that often the original lot has been processed, distributed and consumed by the time test results are available. However, if test results are available immediately, the first lot would be detained.

40 We note that, especially in the case of imported products, a policy, which calls for measures to be taken only after a second lot by the same processor or importer, has been found to be non-compliant may not always be effective in ensuring that these products are kept off the market. As indicated in paragraph 65, there are considerable delays in providing results of tests. These delays could allow importers to distribute contaminated products in Canada while the the Agency is waiting for the test results.

Recommendation

CFIA should not use Health Risk Assessments as precedents to redefine actionable levels of administrative MRLs. CFIA should clarify its procedures to ensure that contaminated lots are treated in a consistent manner and are prevented from reaching consumers.

Agency Response

Agreed. In 1999, the CFIA established the Office of Food Safety and Recall (OFSR) as a single window service to coordinate risk management decisions with respect to food safety issues. All CFIA programs advise the OFSR of unsatisfactory results as soon as they are available, for assessment and coordination of further action. When a Health Risk Assessment is required, CFIA technical specialists contact Health Canada, and the OFSR ensures the appropriate risk management steps are taken.

The creation of the OFSR is a significant enhancement to CFIA's emergency response structure and contributes to the overall consistency of CFIA's risk management approach.

The CFIA investigated the root cause when raw aquacultured molluscs were contaminated

41 Molluscs are monitored in Canada, through the 1948 Memorandum of Agreement between the U.S. Public Health Service and the Department of National Health and Welfare (now Health Canada). The Canadian Shellfish Sanitation Program (CSSP) was implemented as a result of this agreement (see paragraph 95). The bacteriological quality of raw molluscs is evaluated by measuring the level of coliform bacteria (fecal coliforms and/or *E. coli)*. These bacteria are usually associated with human sewage; hence they are used as an indicator of the presence of faecal contamination. These coliform bacteria are also indicators that other enteric bacteria may be present. Since bivalve molluscan shellfish may be eaten raw, they could present a potential health concern if they contain these coliform bacteria.

42 Guidelines for these bacteria were developed and accepted, for both shellfish growing area water classification and the bivalve molluscan shellfish themselves, by both the U.S. and Canada. The Department of National Health and Welfare (now Health Canada) as the federal agency with the lead for the shellfish program was involved in the development, acceptance and implementation of these guidelines. Over the years, the main responsibility for CSSP was transferred from National Health and Welfare to the Department of Environment (now Environment Canada) and then to DFO, although all these departments remained involved, for instance through the Interdepartmental Shellfish Committee. In 1993, DFO replaced faecal coliform analysis with generic *E. coli* analysis in a revised version of its bacteriological guidelines. These guidelines are now used by CFIA. We note that they are consistent with internationally recognized standards for faecal coliforms and *E. coli.*

43 We reviewed 19 cases of domestic raw molluscs from aquaculture establishments that had exceeded CFIA's bacteriological guideline. They had been tested by the Agency as part of QMP routine checks or for certification purposes at the plant level. We noted that for all cases reviewed, the Agency investigated the root cause in order to prevent the problem of recurring. However, we found that prior to the creation by CFIA of the Office of Food Safety and Recall (OFSR) in July 1999, in a substantial proportion of cases (8 cases out of 19), the Agency did not initiate recalls when its bacteriological guidelines had been exceeded. Recalls were conducted for the two cases which occurred after the creation of the OFSR.

44 As noted above, Health Canada has, since the inception of the CSSP in 1948, participated in a number of interdepartmental meetings and exchanges pertaining directly and indirectly to discussions related to the establishments of the guidelines presently used by CFIA (i.e., 230 *E. coli* per 100 g.) However, in May 1999, Health Canada issued an interpretative summary of its standards and guidelines for microbiological safety of food. In this document, the standard for several types of ready-to-eat products is different.

45 As is specified in the Memorandum of Understanding on Food Safety Emergency Response between Health Canada and CFIA, it is ultimately the responsibility of Health Canada to provide the Agency with standards, policies and guidelines covering food safety. Once a standard is established, it is expected that the Agency will implement it. Health Canada will continue consultations with the CFIA regarding establishing specific food safety guidelines for a variety of seafood products, including molluscan shellfish.

CFIA uses recognized analytical methodologies

46 In an organization like CFIA, which conducts numerous laboratory tests on a variety of products, it is important to ensure that the methodologies are consistent across the organization and are properly validated.

47 The Agency's procedures for assessing the microbiological safety of fish and fish products are derived from its *Standard Procedures for Bacteriological Analysis* manual of CFIA, the Compendium of Analytical Methods of Health Canada and the Bacteriological Analytical Manual of the United States Food and Drugs Administration (US FDA). CFIA Microbiology laboratories participate in a Quality Assurance Program with the US FDA by carrying out proficiency tests of staff in detecting pathogens in food sample. In addition, laboratory staff carry out tests every three months on a national basis to ensure the accuracy of the methodologies used.

48 In general, the procedures used to determine the level of drug residues, chemical contaminants and pesticides are found in CFIA's *Chemical Method Manual*. The criteria for including a particular method in the Methods Manual are the following:

- It must be accepted by the Association of Analytical Chemists (AOAC), or Health Products and Food Branch (formally Health Protection) and have been checked by a CFIA Fish Inspection Laboratory as to its applicability to fish and fish products;
- It must be routinely used in a CFIA Fish Inspection Laboratory, and its results must be supported by a national or international check sample program; and
- It must be proposed by a CFIA Fish Inspection Laboratory and validated by an acceptable collaborative study.

49 Methods that are being used, but which are not included in the Chemical Method Manual are validated in-house for their performance. CFIA Chemistry laboratories conduct proficiency tests annually at the national level on various contaminants and drugs. They also participate in check sample studies at the international level for veterinary drug residues. For example, one laboratory participated in the Food Analysis Performance Assessment Scheme (FAPAS) in 1998.

50 We noted in paragraph 27, that the Agency doesn't test for some drugs that the aquaculture industry is currently using. For example, Florfenicol is currently being used in the Western Area and Emamectin Benzoate is being used widely in Atlantic Area as shown in Exhibit 3 and 4. Following the application for approval of veterinary drugs, Health Canada normally forwards the methodology provided by the pharmaceutical company to the Agency. CFIA laboratories then adapt and validate the methodology for routine analytical testing. With respect to Florfenicol, Health Canada did not provide the methodology to the Agency. We also found no evidence to indicate that the Agency made a formal request to Health Canada to obtain the methodology. The methodology has recently been provided to the Agency. In the case of Emamectin Benzoate, this drug is a relatively new product used by the industry since 1998, under temporary authorizations issued by Health Canada (as explained in paragraph 21). The pharmaceutical company has provided a methodology for this drug to both Health Canada and CFIA in April, 2000. The Roles and Responsibilities Framework for Federal Food Safety and Inspection Activities specifies that Health Canada has the lead role to develop analytical methodologies. CFIA also has a complementary role in that area.

51 We also noted that the CFIA Ontario Chemistry Laboratory was using Charm tests to test for the presence of three classes of antimicrobials, i.e., Tetracyclines, Amphenicols and Sulfonamides. A Charm test is a method that quickly detects traces of certain classes of antimicrobial drugs in products. If traces are detected, a more thorough laboratory test must be done to determine the exact level of the specific drug in the product. This approach avoids the need for extensive testing of all samples. If this technique meets all the performance and validation criteria in evaluations before their use is extended to all CFIA laboratories, it could be a good means to improve the efficiency of testing.

Recommendation

CFIA should work with Health Canada to develop a mechanism for the ongoing exchange of information concerning veterinary drugs used.

Agency Response

The CFIA has taken measures to encourage information exchange on the issuance of temporary drug authorizations and on general therapeutant use, including the establishment of the Interdepartmental Committee on Therapeutant Use in Aquaculture.

The documentation available on complaints is incomplete

52 The Agency has a policy and procedures governing the investigation of consumer and trade complaints with respect to fish and fish products. The policy is adapted by the Areas to reflect relevant agreements with the provinces.

53 From April 1997 to November 1999, the CFIA investigated 107 consumer complaints involving illnesses associated with fish products. In order to determine whether the investigations of consumer complaints were consistent with existing policies, guidelines and directives, we reviewed 15 cases that involved illnesses and possibly aquacultured fish products. In 9 of the 15 cases, provincial agencies carried out investigations. In four other cases, the Agency did the work and, in the two remaining cases, investigations were done jointly by the provinces and the Agency. We found that in almost all cases, documentation was incomplete and that it was not possible to evaluate the appropriateness of the investigations. We noted that in three cases, the reported symptoms were allergic reactions, and there is no evidence to show that the presence of drug residues, which are recognized to be potential allergens, was investigated as a possible cause.

More information on lobsters kept in pounds is needed

54 Lobsters are not usually considered to be aquaculture products. Indeed there are no commercially viable operations that have succeeded to raise lobsters from eggs, unlike salmon or trout aquaculture production. However, once wild lobsters are captured they can be kept in captivity for periods ranging from a few days to six months before they are shipped to market. When large numbers of lobsters are kept in a limited space for a period of time, they are more susceptible to disease, especially in warmer weather. Therefore they may be medicated to control disease. For this reason, they present some similarities with aquaculture products in terms of food safety.

55 Lobsters kept in pounds (i.e., holding facilities) for a sufficiently long period of time to be fed and medicated represent a subset of the 43,000 metric tons of lobsters produced in Canada in 1999. There is however no reliable figures on the actual volume of lobsters kept in pounds and medicated. According to DFO, there are 264 pounds in New Brunswick and Nova Scotia. A paper on the lobster holding industry prepared by staff of the Office of the Commissioner for Aquaculture Development quotes estimates indicating that lobster pounds could have a total storage capacity of 4,000 metric tonnes.

56 The Agency carries out only limited testing for drug residues in domestic and imported live lobsters. Prior to the creation of the Agency, when the Fish Inspection Program was still under the jurisdiction of DFO, 124 routine analyses were conducted, from 1992 to 1995, to determine the levels of Oxytetracycline in lobsters. Seventeen of these tests showed levels equal or greater than 0.1 ppm of Oxytetracycline, the administrative maximum residue level permitted for this drug (all from the calendar year 1993). From 1996 to March 2000, the Agency carried out only five tests for Oxytetracycline in lobsters (3 routine, 1 certification and 1 research). These tests detected no residues.

57 In summary, there is limited data available on the extent of drug usage in lobsters held in pounds and on the levels of drug residues in these lobsters. As a result, the Agency does not know the extent to which lobsters meet the requirements regarding the administrative maximum permissible levels of drug residues that they may contain.

Recommendation

The CFIA should increase its monitoring activities for drugs in pound held lobsters.

Agency Response

The CFIA is conducting an investigation to assess the extent of medication use in the domestic lobster pound industry. Preliminary analyses of domestic lobsters samples have not yielded any detectable levels of drug residues. Further analyses are being conducted.

A monitoring program with respect to imported lobster has also been initiated. Preliminary testing has not found any detectable levels of drug residues. In addition, lobsters from the USA are subject to the US Seafood Rule and its associated requirements pertaining to drug use.

More information on aquaculture fish processed in non-federally registered establishments is needed

58 As explained in paragraph 6, the *Fish Inspection Act* gives to the CFIA the authority to inspect fish plants that produce for international and interprovincial markets. These plants are referred to as federally registered establishments. The Agency is also responsible to enforce the *Food and Drugs Act* which applies equally to all food whether traded intra or inter-provincially. Plants involved in intra-provincial trade are referred to as non-federally registered establishments. They may be inspected by the provinces. In some provinces there is no distinction between federally and non-federally registered establishments. For instance, Nova Scotia requires all fish plants to be federally registered. British Columbia has similar requirements for plants processing bivalve shellfish or farmed salmon or trout.

59 A number of non-federally registered facilities process aquaculture fish throughout Canada. According to CFIA officials, there are 78 non-federally registered processing establishments in Ontario where the largest production of freshwater aquaculture fish is located. Also, CFIA has information about more than 260 non-federally registered growers of fish, mostly trout. Growers can sell directly to retail establishments in their province of origin. Trouts represent a relatively modest percentage of all aquaculture fish produced in Canada (8%). Furthermore, according to CFIA officials, a small proportion of trouts are processed in non-federally registered establishments. Health Canada conducted a project in non-federally registered establishments, from 1993 to 1996, where186 fish samples, 77 % of which were for trout, were taken from growers and analysed for the presence of veterinary drugs. None of the tests indicated levels of veterinary drugs above administrative maximum residue limits (AMRL). For the period and Areas covered by our assessment, the Agency has no information on the levels of veterinary drug residues in products coming from non-federally registered facilities from neither its own monitoring nor from the inspections done at the provincial level. This does not mean that there was no inspection or control at the provincial level, but as explained in paragraphs 91 and 92, mechanisms providing for exchange of information were not implemented. This information would be useful to CFIA to support a risk based approach. In this assessment we chose to concentrate on information expected to be available from CFIA as it is the focus of our legal mandate and not to gather and assess information directly from the provinces.

60 The former CFIA Consumer Food Products Program which inspected the non-federally registered facilities is now part of the Bureau of Food Safety and Consumer Protection. On March 31, 2000, after the completion of this assessment, the Agency implemented a redesign of the Consumer Food Products Program CFIA indicates that the program, now called the Food Safety Investigation Program, enforces the safety and nutritional quality provisions of the *Food and Drugs Act* by investigating consumer and industry complaints and taking appropriate enforcement actions to contribute to the safety of the food supply. The program also undertakes preventative measures, using a risk based approach, to promote compliance with the provisions of the *Food and Drugs Act* .

Recommendation

The CFIA should take into account aquaculture products processed in non-federally registered establishments when planning the activities of its Food Safety Investigation Program.

Agency Response

The CFIA estimates that less than two percent of all finfish are not processed in federally registered establishments. Jurisdiction for establishments that are not federally registered is shared with the provinces. The aquaculture assessment did not assess the level of inspection or testing conducted by the provinces in these establishments.

The CFIA's Food Safety Investigation Program takes into account aquaculture products processed in non-federally registered establishments when planning its activities. The Program investigates consumer and industry complaints on all food products including fish. Complaints are thoroughly investigated at the consumer, retail, distributor and manufacturer level. The CFIA takes action, including food recalls, to ensure that food safety risks are addressed and that industry takes action to prevent a recurrence.

The Food Safety Investigation Program also undertakes projects to promote compliance with the *Food and Drugs Act*. Science and technical committees conduct a risk assessment and priority setting process to identify the projects to be conducted each year. During their assessment process, the committees consider information on a wide range of food safety risk, including information on aquaculture products.

C. Service Standards

The wording and tracking of service standards could be improved

61 The Government of Canada has stated repeatedly that it is committed to delivering quality services within available resources. Service standards constitute a good tool for defining the level of service clients can expect. At the same time, standards enable the organization that provides them to keep track of its performance. In 1994, the DFO, which was then responsible for inspecting federally registered fish processors, recognized the usefulness of service standards and developed standards for its inspection operations. Standards were developed to demonstrate the commitment of the fish inspection program to providing a consistent level of national service to Canadian consumers and the fish and seafood industry. The Agency has retained these service standards and still uses them. For this assessment, we focussed on service standards which pertain more specifically to aquaculture, i.e., the turnaround time for laboratory analyses. They are listed in Exhibit 7.

Exhibit 7
Selected Service Standards Relevant to Aquaculture – Fish Inspection

Imports
Bacteriological and chemical analyses started within 3 working days of sampling(...)

QMP
Plant Inspection: QMP inspections to be completed within 5 working days of commencement and all analyses to be completed within 10 days of sampling, except for Listeria.

Product Inspection: Analysis to begin within 3 working days of sampling.

Product Certification: Chemical and bacteriological analyses to be started within 3 working days of sampling and the analyses completed within 10 days, except for Listeria.

Source: Canadian Food Inspection Agency, Fish Inspection, 1999

62 The Treasury Board publication *Service Standards: A Guide to the Initiative* explains that in the case of service standards pertaining to delivery targets such as timeliness it is important to ensure that:

- they are clear to the client;
- they relate to those aspects of service that are important to the client; and
- they are measurable.

63 We noted that there was room for improvement in all of the above. For instance, the reasons underlying the inconsistency among the standards listed in Exhibit 7 for analyses done for imports, plant inspections, etc. are not clear. The wording of some standards is also questionable. For example, certain standards call for analyses to be "started within X days." Such a standard may be useful for internal management purposes, but it is of little relevance to consumers and the industry who are more interested in the time taken to "complete" the analyses (the terminology used in other instances.) Another problem relates to the decision to express the standards in "working days," an approach that is not very useful where timeliness directly affects the safety of products that could be consumed. Finally, although service standards were sometimes included in the Agency's planning documents, we found only limited evidence that it had actually tracked its performance against them.

64 In some cases the Agency provided us with data that allowed us to calculate the performance of the analyses (i.e., the turnaround time for analyses) pertaining to aquaculture products for certain inspection activities. Exhibit 8 shows the result of this analysis. To be consistent with the Treasury Board Guide, we measured the turnaround time in calendar days because this measure is more relevant to situations where the health and safety of consumers may be at risk. We also focussed on the turnaround time that was most significant to Canadian consumers and the fish and seafood industry, since these service standards were developed for them: i.e., the time taken to complete the analyses from sampling to reporting the results. The exhibit shows that in the case of microbiological analyses in the Western Area, the turnaround times were short. However, the turnaround times for chemical analyses in the Atlantic Area are substantially longer. The differences in turnaround times do not appear to indicate that one area is more efficient or faster than another. Rather the differences reflect the type of analytical work for which we had data. If so, it may warrant the development of distinct targets for microbiological and chemical tests (contrary to the 1994 service standards which set the same target for both.)

Exhibit 8
Average Time (calendar days) for Completion of Analysis* in Canadian Food Inspection Agency, Fish Inspection Laboratories

Laboratory	Area/Location	1997/1998	1998/1999	1999/2000
Domestic Product				
Chemistry	Atlantic (Halifax)**	22.6	17.8	18.8
Microbiological	Western (Vancouver)	5.4	5.4	5.5
Imported Product***				
Drugs and Pesticides	Western (Winnipeg)**	25.8	37.9	53.0
Drugs and Pesticides	Atlantic (Halifax)	37.0	21.7	20.5

* From date sample is taken to date analyses results are reported

** The chemistry results for these domestic products are reported by calendar year of Jan. to Dec.

*** According to the Canadian Food Inspection Agency (CFIA), the initial date recorded is not the date the sample was taken but is the date the information pertaining to an importation is entered in CFIA's information management system. This data entry is usually done one or two days after CFIA is notified of the importation. Since the CFIA "Guide To Canadian Regulatory Requirements and Examination for Imported Fish", specifies that products new to the Canadian market are sampled on entry, we considered it a reasonably close approximation of the sampling date. It must be noted that the real turnaround time may be slightly shorter.

Source: Canadian Food Inspection Agency, Fish Inspection Program, 2000

65 For tests on imported products, the results we compiled indicate considerable delays. Some improvements were noted in 1999-2000 in the Atlantic Area. However, the delays observed are still a concern, especially in the light of the comments made in paragraph 40. In the case of the Winnipeg laboratory we noted a notable decline in performance in 1999-2000. CFIA indicates that the increasing delays over the past two fiscal years occurred in part because samples were batched and shipped from Toronto to Winnipeg for testing. Drug testing is no longer done in the Winnipeg laboratory – this work was transferred to the Mississauga laboratory in 1999.

Recommendation

CFIA should pursue and extend the implementation of its service standards pertaining to aquaculture products. In doing so, CFIA should ensure that:

- Standards are expressed in a clear and consistent manner compatible with the varying nature of the activities monitored and the level of risks to health involved.

- The standards are tracked and monitored consistently in order to provide management information that could contribute meaningfully to decision-making.

Agency Response

CFIA agrees that service standards, specific to laboratory testing of all fish products, should be updated. The Treasury Board Guide will be referred to during this process to ensure that the standards are clear, relevant and measurable. Standards applicable to lab testing will be tracked and monitored using laboratory information management systems.

II. Inspection Activities Related to Feeds Used in Aquaculture

66 CFIA inspects feeds continuously. However, its inspection activities could be more effective if they covered all species and all drugs prescribed, and if the Agency followed-up more rigorously on cases of non-compliance especially those related to excessive levels of drugs in feed; the safety of any food for humans derived from animals consuming contaminated feed could be affected.

67 Most drugs prescribed to aquacultured fish are administered through their feed. Moreover feed could be contaminated with micro-organisms, pesticides residues, herbicides, heavy metals and industrial chemicals that can also pose risks to human health via the food derived from the animals that consume it. This contamination could occur because of faulty processing and preparation, or if contaminated additives, ingredients and binding agents are added to the feed.

68 CFIA inspection of feeds for all livestock includes inspecting the products from 400 to 500 commercial feed mills and farms every year. The Agency also indicates that along with sampling approximately 6,000 feeds for such things as biological and chemical contaminants it regularly monitors drugs in feeds. Fish feed inspection is not specifically identified in feed regulatory work but is carried out at a level that reflects the size of the industry (i.e., between 3 to 5% of total livestock feed production.) CFIA also monitors activities in HACCP pilot plants, carries out label enforcement activities, and various investigations when warrented. It also handles fish farmer's complaints.

A. Feed Regulations

The definition of "livestock" in the *Feeds Act and Regulations* does not cover lobsters and many aquaculture species

69 The *Feeds Act and Regulations* regulate the manufacture, import and sale of all livestock feeds, "livestock" being defined in the *Act* as cattle, swine, poultry, fish, sheep, goats, horses, rabbits, mink and foxes. The Feed Program performs tasks such as review and monitoring of feed medication levels, usage, direction for use and drug withdrawal times as well as product label; registers certain categories of feed; and undertakes toxicological assessments of new feed ingredients. The *Feeds Act and Regulations* focus on product standards and not on the process, therefore they regulate only the products that fall within the regulations as determined by its definitions (e.g., livestock.)

70 The definition of "livestock "in the *Feeds Act and Regulations* includes few aquaculture species. As wild fisheries are threatened and aquaculture expands, different species of fish (arctic char, tilapia, perch, etc.) are being farmed. We also noted in paragraph 54 that some lobsters kept in pounds may be medicated and as such present some similarities with aquaculture products in terms of food safety. The Feed Program has restricted the scope of its activities to feeds for finfish of food species like salmon and trout and as a result, feed for other aquaculture species, either domestically manufactured (feed mill or on-farm) or imported, is not included in CFIA's Feed Program sampling or inspection plan. Consequently, the Agency is not required to inspect feed prepared for fish species other than salmonids even though they may contain veterinary drugs.

Recommendation

The CFIA should ensure that the definition of "livestock" used in the *Feeds Act and Regulations* is extended to cover lobsters, crustaceans and other species of farmed fish.

Agency Response

CFIA's proposed legislation, *The Canada Food Safety and Inspection Act*, takes steps to harmonize the definitions contained in CFIA's current legislative base. It contains a definition for "Aquatic Commodities" which includes, among other things, "fish, shellfish, crustaceans, marine animals and parts of any of those things." Passage of this proposed legislation will harmonize the definitions used throughout Agency programs.

In addition, CFIA has proposed Regulations Respecting the Making of Medicated Feeds. Under this proposed legislation manufacturers of medicated feeds for lobsters and all other food and food-producing animal species will be subject to licencing by CFIA. The licencing requirement will provide CFIA with better information about farm locations, medication usage, feed manufacturing and handling practices.

In the interim, CFIA has determined that it is possible to refer to the *Fish Inspection Act*'s definition of "fish" when interpreting the word "fish" contained in the *Feeds Act*'s definition of "livestock." The former is a broad definition of fish which includes lobsters and other crustaceans. CFIA will investigate the resource implications of these additional regulatory responsibilities.

B. Coverage of Feeds Inspections

The Inspection coverage of Feed Mills by the Feeds Program is satisfactory, but the testing of drugs is not comprehensive

71 The Feed Program works on a three year cycle, during which CFIA aims to inspect all the feed mills under its jurisdiction. We noted that nine of the ten feed mills that the Agency had identified as producing medicated fish feed had been inspected during the three year cycle.

72 To complement its plant inspections, the Agency also collects samples of medicated fish feeds to better assess in-plant controls over these products. The national sampling program target the drugs listed within the Compendium of Medicating Ingredient Brochures (CMIB). Although four antimicrobials are approved for use with fish feed in Canada (see Exhibit 2), CMIB lists only Oxytetracycline. From 1997 until present, the Atlantic Area Feed program inspectors have been submitting medicated fish feed samples for analysis only for Oxytetracycline. As demonstrated by our compilation of prescriptions, in 1999 Oxytetracycline represented only 30 % of all drugs prescribed and administered through fish feeds in the Atlantic Area. Furthermore in 1999 in the Atlantic Area, 65% of all the prescriptions were for unapproved drugs (Emamectin Benzoate) or "off-label" drugs (Ivermectin). We also note that the feed laboratory was not provided with the methodology to analyse one of these unapproved drugs (Emamectin Benzoate).

73 During the same time period, inspectors with the Western Area Feed Program submitted medicated fish feed samples for analysis for a variety of approved drugs despite the CMIB limitations noted above. According to our information on prescriptions, these drugs accounted for 99% of prescriptions for medicated fish feed in the Western Area. Therefore in the Atlantic Area, the practice of testing only for drugs listed in the CMIB means that inspectors are not testing for all drugs which the aquaculture industry is using in fish feeds.

Recommendation

The CFIA should ensure that the annual National Feed Inspection Program tests for the full range of drugs currently used by the aquaculture industry.

Agency Response

The National Feed Inspection Program is designed to test for the full range of "over-the-counter" drugs (available without a prescription) currently approved by Health Canada for use by the aquaculture and other livestock industries in Canada. In addition, the program tests for such drugs in feeds when prescribed at non-approved dosage levels or for other species. However, there are situations where Health Canada makes drugs available through other processes, i.e. temporary authorizations or off-label veterinary prescriptions. CFIA will work through the Interdepartmental Committee on Therapeutant Use in Aquaculture to investigate the implications of testing feeds for drugs made available through these processes.

The Feed Program does not conduct inspection of on-farm production of feeds in aquaculture facilities

74 We learned through interviews and visits to feed mills, that on-farm medicating of fish feed is occurring in the Western and Ontario Areas. This practice is a potential hazard if farmers introduce an excessive amount of medication to fish feed. When the fish consume the feed there is a risk that residues of the medication will be present in their tissues when they are processed. Feed program inspectors visit farms as part of an established inspection program as well as in the context of investigating complaints. However no on-farm inspections of aquacultural sites have been carried out since April 1, 1997 by any of the Feed inspectors in the three operational Areas that we reviewed during our assessment. In any event their tasks would have been impeded by the fact that the CFIA Feed Program has no national listing of farms (including aquaculture farms) and the scarcity of information available on the current extent of on-farm practices in the aquacultural industry.

Recommendation

CFIA should conduct inspections of medicated feed production carried out at aquacultural production sites.

Agency Response

Through the On-farm Inspection Program component of the National Feed Inspection Program CFIA staff inspect and assess medicated feed compliance with the Feeds Regulations. The On-farm Inspection Program specifications will be modified by CFIA to more clearly include the inspection of aquaculture production facilities as a part of the scope of the program.

Once the CFIA's proposed Regulations Respecting the Making of Medicated Feeds are implemented, all farm-based livestock producers who wish to make medicated feeds will be subject to licencing by CFIA.

C. Service Standards

The turnaround time of laboratory analysis could be improved

75 The CFIA Feed Laboratory has established service standards based on turnaround times for analysing feed samples. These standards have been in place for about 10 years and are listed in the annual National Program document for particular types of samples. The Agency's performance in meeting these standards is summarized in Exhibit 9. It shows that the average turnaround times for analysing fish feed samples exceed the targets set for some sample programs.

Exhibit 9
Feed Laboratory Turnaround Times in Calendar days on Therapeutant Analysis on Fish Feed Samples Submitted Between April 1, 1997 and December 31, 1999

	Program 60A*	Program 42**	Program 35***
National Feed Inspection Program Service Standards	45	21	21
Average Turnaround	69.4	53.7	48.8
No. of samples submitted	23	10	6

* 60A - (Feed Mill) Medicating Ingredients - Guarantee Verification
** 42 - Drug Residue Contaminants - Feed Mill (product)
*** 35 - Surveillance for Inspector's samples

Source: Canadian Food Inspection Agency, Feed Program, 1999

76 The delays in analysing samples of fish feed are due mostly to the low number of samples received. Samples are saved and analysed in batches rather than when they are received. It is worth noting that for all drugs for which the CFIA Feed laboratory has a valid testing method, the average withdrawal time for drugs (e.g., 6 months for Ivermectin) exceeds the turnaround time calculated by the Agency (6 to 8 weeks). Although earlier notifications of non-compliance are always desirable from a health and safety perspective. However, we note that despite these delays if a sample result indicates that a feed containing more medication than is indicated on the label, it is not too late for the Feed inspector to notify the prescribing veterinarian or fish farm of the concern and thus prevent residues from appearing in slaughtered fish.

77 In some cases, delays could be of more concern. In 1998-99, the Agency carried out an investigational survey to collect and test samples of fish oil and fish meal for environmental contaminants such as PCBs and DDT. The intention was to use the information from the survey to set policy for acceptable maximum levels for these contaminants in feeds and re-evaluate the current level set for PCBs. Environmental contaminants in feeds have been a concern since the 1980s of DFO and the Feed Laboratory (then under Agriculture Canada). However, in December 1997, an incident involving fish oil imported in Canada that had been contaminated with DDT, highlighted the need for such a survey. Aquaculture activities could be affected by contaminants in fish oil and fish meal, which make up a large part of many manufactured fish feeds.

78 We found that, at the time of our assessment, samples of fish meal and fish oil taken more than two years ago as part of the survey had not yet been analysed due to equipment difficulties and other urgent demands that required a reallocation of resources. After two years, the usefulness and relevance of these analyses may be limited. The Agency indicates that the delay of two years does not diminish the usefulness of this survey. However, this delay has prevented the timely development of a policy for these contaminants as well as the establishment of a routine testing program, if the Agency deems it necessary.

Recommendation

The CFIA should improve the turnaround time for the analysis of levels of drugs and environmental contaminants in feed.

Agency Response

The CFIA agrees that every effort must be, and is being made to improve turnaround times for these analyses. Improvements are being made by attempting to improve the efficiency of methods and procedures and through prioritization.

D. Follow-up Procedures and Program Review

The follow-up procedures in some cases of non-compliance are inadequate

79 Exhibit 10 shows the results of the inspection programs that were relevant to aquaculture. In terms of risks to human health, samples of feed showing levels higher than what is specified on the label (referred to by CFIA as "excessive guarantee") are more of a concern. Producers who administer the medicated feed have to allow for a withdrawal period, indicated on the prescription, to ensure that the drug is fully metabolized by the animal before it is processed for market. The withdrawal period is a function of the level of drug in the feed. Therefore it is possible that fish prepared for human consumption could contain a drug residue in their tissues if the feed were to contain higher levels of drug than indicated. Feed containing insufficient medication are also a health risk. However, the risk is more hypothetical and long-term because "under-medicated" feeds could be associated with the development of antimicrobial resistance in humans. This is so because even though fish diseases do not affect humans there is a possibility that non-target pathogens impacting on humans and found on some fish or living in their environment could develop increased resistance to antimicrobials. As mentioned in paragraph 10, Health Canada is presently conducting, with the participation of CFIA, a study on this issue.

Exhibit 10
Feed Laboratory Drug Guarantee (Programs 60A* & 35) Analysis Submitted for Medicated Fish Feeds Submitted Between April 1, 1997 and December 31, 1999**

Area	Total Samples Submitted	Satisfactory[1] Samples	Deficient[2] Samples	Excessive[3] Samples
Atlantic (NB&NS)	13	10	3	0
Western (BC)	14	5	6	3
Ontario	0	0	0	0
Total	27	15	9	3

* 60A - (Feed Mill) Medicating Ingredients - Guarantee Verification
** 35 - Surveillance for Inspector's samples

[1] Within tolerances of prescribed levels of drugs. Tolerances in *Feeds Act and Regulations* Section 25(2), Schedule I, Table 2
[2] Less than 20 % of prescribed level
[3] Greater than 20 % of prescribed level

Source: Canadian Food Inspection Agency, Feed Program, 1999

80 Before December 1999, the Agency had neither any guidelines nor a formal national compliance policy to guide Feed Program inspectors in dealing with non-compliant feed samples. CFIA officials told us that when feed inspectors found non-compliant samples, they notified the mill of the results either by phone or by letter and asked the mill to correct the problem. However, for the 12 samples (out of 27) that were found to be not compliant (See Exhibit 10), we found no documented evidence that formal investigations, reinspections or follow-ups on medicated fish feed samples were carried out as part of a regional feed program.

81 Currently, the CFIA Feed Inspection program has issued the "Guide on Conducting Follow up Inspection of Out of Compliance Samples." This Guide details the process that the feed inspector should follow when samples are found to be non-compliant. It specifies that a follow-up should be carried out at the feed mill to identify the source of problem. It also describes the hazards of excess and deficient levels of medication in feed. However, nothing in the Guide indicates that CFIA staff should notify the prescribing veterinarians or the fish farmer directly when a feed with excessive level of medication has been found. Without direction in this area the CFIA is relying on the honour system, given that the feed mill is responsible for notifying customers about problems related to the levels of drugs in the feed they purchased.

The CFIA has proposed new regulations for medicated feeds

82 The Canadian Food Inspection Agency is indicating that it will address the issues raised in the previous paragraphs with respect to follow-up procedures through the proposed new regulations which will require licensing and upgraded control measures for manufacturers of medicated animal feeds in Canada. The new feed regulations being proposed under the authority of the *Health of Animals Act - Regulations Respecting the Making of Medicated Feeds* were published on February 5, 2000 in the *Canada Gazette* Part 1. The objective is to enhance the safe handling and use of medication in feeds. The CFIA anticipates that the creation of a national registry of medicated feed manufacturers and the obligation to adhere to manufacturing controls and record-keeping will facilitate trace-backs of incorrectly manufactured feed or potentially contaminated food in the event of a recall. This Assessment could not report on the effectiveness of the new regulations. Their impact on the issues raised in the assessment will have to wait for promulgation of the regulations and their implementation by the Agency.

Recommendation

The CFIA should continue to improve its guidance on follow-up for out of compliance samples in order to ensure that feed containing excessive levels of medication are properly monitored. In particular it should ensure that aquaculture growers are properly informed about non-compliant fish feed.

Agency Response

Agreed. The CFIA has developed follow-up enforcement guidelines for non-compliant results concerning medicated feed and drug residue in feeds for all regulated species. These guidelines were implemented in the fall of 2000 and incorporated into the National Feed Inspection Program for the 2001-2002 fiscal year.

Audits of the Feed Program were conducted

83 CFIA audited its Feed Program in the Ontario Area in February 2000, in the Atlantic Area in October 1999 and in the Western Area in March 1999. The Ontario and Atlantic Area program audits were carried out under the new CFIA Generic Program Audit Protocol. The Western Area review was done under the original Feed Program audit and review program. The report on the results of the Ontario audit had not been completed when this report was being prepared. Although the Western Area audit addressed a number of issues explicitly related to aquaculture, we note that the Atlantic Area audit did not.

84 The program audits include program delivery (e.g., inspections), communications, program design, safety, tools, training and sampling issues. These audits allow the feed program staff to review the operational adherence to the National Feed Program Work Plan and facilitate monitoring its activities. The program audits are useful program management tools. However, it is essential to follow-up on issues identified in the audits in a timely manner to ensure that they contribute to improving the program.

85 We noted that in the Western Area, the Agency had not yet followed up on several items identified by the audit, even a year after it had been completed. The unclear attribution of responsibility for the follow-up on these items, is the reason for a lack of timely resolution of some of the issues addressed in the audit, according to CFIA officials. CFIA expects that its new Generic Program Audit Protocol will enable it to follow-up on corrective actions in a more timely manner.

III. Roles and Responsibilities

A. Agreements with Key Provincial Governments

86 Agreements with provincial governments that could lead to fewer gaps and less duplication in inspection activities were in place before the Agency was created. However, to date the information exchanged between the parties has been minimal. The new agreements that are being negotiated will provide for better exchange of information.

Memoranda of Agreements are in place

87 The Canadian regulatory framework for aquaculture is complex and involves a multitude of partners, given that the safety of the food supply is a shared jurisdiction in Canada. Therefore, it is a substantial challenge to ensure that this framework is effective in regulating and controlling food safety at the production, manufacturing, retail, transportation, import, and food service levels. Incorporating an integrated inspection system into this framework represents another challenge.

88 CFIA has repeatedly stated that its goal is to improve inter-governmental co-operation by both reducing overlap and duplication, and streamlining service delivery. Many strategies have been used to achieve this goal. With respect to aquaculture, federal-provincial agreements established on a bilateral basis have been used for many years. When the Agency was created in April 1997, it became responsible for a number of Memoranda of Understanding (MOUs). These MOUs pertained to all types of fish, although a number of them referred specifically to aquaculture in appendices, especially those signed by DFO with the provinces in the mid-nineties. Agreements between Health Canada and provincial governments (signed in the eighties) also included aquaculture since they covered all foods.

89 A study on collaborative arrangements published in 1999 by the Office of the Auditor General (OAG), identified a number of key elements needed for strong accountability. With respect to the regulation of aquaculture products, we looked at some key elements – the importance of clear roles and responsibilities and credible reporting through mechanisms that promote discussions, cooperation and good exchange of information.

90 In relation to aquaculture, we focussed more specifically on MOUs with Nova Scotia, New Brunswick, Prince Edward Island, British Columbia and Ontario. The agreements that we reviewed did contain many of the elements mentioned by the OAG. For instance, the MOU between DFO and one of these provinces, contained clauses establishing a joint Fish Inspection Committee, that would coordinate the implementation of the MOU and meet at least once a year. It also included clauses specifying that the province would, among other things, provide the results of inspection, investigations and analyses related to health hazards and safety. Finally, the MOU specified that the Province would notify its federal counterpart in case of any unsatisfactory findings pertaining to fish and that it would provide assistance, especially during crisis situation. These MOUs pertained exclusively to the responsibilities previously retained by DFO under the *Fish Inspection Act*. The MOUs between Health Canada and the provinces covered all food under the *Foods and Drugs Act*. They attempted to clarify the respective roles and included clauses on exchanging information.

Key elements of the MOUs have not been implemented

91 We also examined how these MOUs have been implemented. We noted that some meetings of the joint Fish Inspection Committees have been held with ad hoc communication, in many instances triggered by crisis or emerging issues. However, we found only limited exchanges of information between CFIA and the provinces since its creation.

92 This lack of information causes concern since it is essential to ensure that gaps and duplication are avoided between the CFIA and its provincial counterparts. Gaps are a concern because they could reduce the level of assurance in the safety of the food supply. On the other hand, overlap and duplication could lead to ineffective and inefficient use of resources, and increased regulatory burden. In the absence of information on provincial activities, the Agency could miss opportunities to both ensure that all aspects of food safety are properly covered, and prevent redundant inspections and tests.

93 As stated in the OAG study on collaborative arrangements mentioned in paragraph 89, good, reliable information is the cornerstone of sound accountability relationships. Considering that CFIA in many instances has joint responsibilities with the provinces, and because of its broad mandate to enforce the *Food and Drug Act*, it is essential for the Agency to know how the provinces are fulfilling their responsibilities, so that it can fill any gaps as necessary.

New Agreements with the provinces are in the process of being negotiated

94 Since its creation in 1997, the Agency has undertaken to negotiate new agreements. A few have been signed and negotiations are underway with others. These negotiations provide opportunities to ensure that the problems of implementation that have been experienced in the past will be avoided. CFIA's approach has been to sign broad "umbrella" agreements with the provinces. These agreements contain broad commitments and statements of intention that will be articulated and operationalized in subsequent agreements or appendices to the umbrella agreements. They are intended to cover all CFIA responsibilities included under the *Fish Inspection Act* and *Foods and Drugs Act*. New agreements pertaining to aquaculture or fish products have not yet been signed. It will be important that the new agreements avoid the problems of implementation noted above and have mechanisms to prevent them from occurring in future.

Recommendation

In negotiating umbrella agreements with the provinces and the subsequent appendices to these, CFIA should ensure that agreements pertaining to aquaculture:

i. define clearly the roles and responsibilities of the respective parties;

ii. include mechanisms to ensure on-going communications; and

iii. foster effective information exchanges.

Agency Response

When the CFIA negotiates agreements pertaining to fish inspection with the provinces the agreements define clearly the roles and responsibilities of the respective parties, include mechanisms to ensure on-going communications and foster effective information exchanges.

Recommendation

Once the new agreements pertaining to aquaculture have been signed, the CFIA should put in place appropriate mechanisms to ensure their implementation.

Agency Response

When agreements with the provinces pertaining to fish inspection are signed, the CFIA puts in place the appropriate mechanisms to allow for effective implementation.

B. Relationships with Other Stakeholders

CFIA co-operates with other federal departments

95 The program that necessitates the highest level of co-ordination of CFIA with other federal departments in the area of aquaculture is the Canadian Shellfish Sanitation Program (CSSP). The main aim of the CSSP is to ensure that the growing areas for all bivalve molluscan shellfish (i.e., clams, mussels, oysters, whole and roe-on scallops and other bivalve molluscs - that can be produced in aquaculture sites) meet approved federal water quality criteria, that sources of pollution of these areas are identified, and that all shellfish sold commercially are harvested, transported and processed in an approved manner. DFO, Environment Canada and CFIA share responsibilities for various aspects of the CSSP. We have found evidence that program coordination is achieved through regular interdepartmental meetings.

96 We also note that the CFIA has proposed creating an Interdepartmental Committee on Therapeutant (Drug and Pesticide) Use in Aquaculture (ICTUA) to facilitate formal discussion on a variety of topics pertaining to the joint responsibilities of various federal departments in the area of aquaculture. Such an initiative would certainly help encourage fruitful exchanges of information and to identify areas where further co-operation is possible.

CFIA has agreements with other countries

97 Since 1997, Canada has had a Mutual Recognition Agreement (MRA) with Thailand a country that exports substantial quantities of aquaculture products (mostly shrimps) to Canada. Under this MRA, both countries recognized that their respective control systems and systems for inspecting fish and fishery products were equivalent. Therefore, they agreed to reduce the frequency of inspection. This reduction affects the standard tests (container integrity, labelling, sensory, etc.) and tests for pesticides which are normally conducted at a frequency of 15%. Drug residues, which are considered a low risk by the Agency are always monitored at a frequency of 5% whether or not there is an MRA. Between 1997 and 1999, Thailand companies under the MRA were subject to a 5% inspection monitoring level for standard tests and pesticides, as opposed to the standard of 15% normally enforced by CFIA.

98 As part of the MRA with Thailand, CFIA audited the control systems of this country in March-April of 1999. This audit identified among others, specific concerns regarding both the limited levels of testing by the Thailand Department of Fisheries, and the fact that Thailand officials were not aware of some Canadian requirements. The audit concluded that the reduced levels of inspection carried out by CFIA under the MRA were unwarranted, and in May 1999, the frequency of inspections for standard tests was increased to 15% . We note that it took two years before the Agency established through its audit that the frequency of inspections of products coming from Thailand should be raised to 15% until the concerns identified would be addressed. The frequency has now reverted to 5%.

99 Canada also has MOUs with other countries that produce aquaculture products (e.g., Ecuador, Philippines and Indonesia.) These MOUs, contrary to the MRA with Thailand mentioned above which covered the entire inspection system, only pertain to specific plants. The plants listed in these MOUs are given a preferred status. We observed that since October 1997 in the case of Ecuador, and April 1997 in the case of Philippines, the Agency has not obtained any information from these countries on the status or compliance of the listed plants. Nor has the Agency carried out any audits to determine whether the plants should continue to benefit from the preferred status.

CFIA encourages the industry to develop initiatives

100 During our assessment, we learned of instances where the Agency encourages the industry to develop initiatives. The Healthy Salmon Program is a good example of a potentially fruitful interface between CFIA and the industry. It is an aquaculture industry initiative developed by *Salmon Health*, an industry-supported organization. It aims at developing a therapeutant use program that is compatible with HACCP principles through the design of an administrative model focussing on the controls and the systems. It is applied by regional industry associations in self-regulation. The information compiled by this program could be used by the Agency in combination with other sources of information to assess the systems in place ensuring the safety of aquaculture products. There are also various joint committees (such as the Shellfish Classification Committees, the Vibrio Advisory Group and various management plans) that provide opportunities to obtain useful information on the industry and increase voluntary compliance in an efficient manner.

CFIA has established a Working Group on Aquaculture

101 The CFIA Aquaculture Working Group was created on November 6, 1998. Its terms of reference are to:

- Serve as the Agency conduit (both intra- and inter-agency) for the communication and dissemination of information on aquaculture issues.
- Monitor and participate in interdepartmental activities associated with aquaculture research, development, production, processing and trade.
- Provide technical information, regulatory and policy advice and regulatory education (to clients) relative to CFIA's aquaculture-related activities (feeds, veterinary biologics, fish inspection and communication, etc.)

102 The Working Group has met five times since November 1998. Considering that aquaculture is a complex field that crosses many program areas within CFIA, such a Working Group could facilitate communication and co-operation between various officials responsible for different aspects of aquaculture and ultimately increase the Agency's effectiveness in this area. For instance, the Feeds Program could get access to the prescriptions. As we have demonstrated in paragraphs 24 to 30, these prescriptions could be used by the Fish Inspection Program to better target its analyses. The Working Group could be a good forum to identify and facilitate such opportunities for co-operation.

Conclusion

103 The following points summarize our key conclusions with respect to each criteria used for the assessment.

Inspection Activities Related to Aquaculture Products

104 Aquaculture has grown rapidly in recent years and now encompasses a variety of products. The presence of veterinary drug residues represents an important key potential hazard in aquaculture products. The Canadian Food Inspection Agency has put in place the Quality Management Program (QMP), an inspection program for fish based on Hazard Analysis Critical Control Point (HACCP) principles. Tests for drugs are conducted regularly on these products as part of a verification of the QMP. Tests results could be more reliable if they were to better reflect the prescription pattern. Compliance with administrative maximum residue limits is high for the drugs that were tested. Furthermore, we found that there is a satisfactory follow-up to investigate root-causes in cases of non-compliance.

Feeds Used in Aquaculture

105 The Agency inspects feeds continuously. However, its inspection activities pertaining to aquaculture feeds could be more effective if they covered all species and all drugs prescribed, and if the Agency followed-up more rigorously on cases of non-compliance. This is especially true for cases related to excessive levels of drugs in feed.

Roles and Responsibilities

106 Agreements with provincial governments that could lead to fewer gaps and less duplication in inspection activities were in place before the Agency was created. However, to date the information exchanged between the parties has been minimal. It is expected that new agreements that are being negotiated will lead to better exchange of information. The Agency also co-operates fruitfully with other federal departments and the industry.

107 In summary, the Canadian Food Inspection Agency is conducting an array of activities to monitor the safety of aquaculture products. It could increase the effectiveness of its food safety programs related to aquaculture products by improving the access to and use of information pertaining to aquaculture products that is often already available or could be obtained with minimal efforts.

About the Assessment

Objective

This assessment will determine the effectiveness of the Canadian Food Inspection Agency activities related to the safety of domestic and imported aquaculture products.

Criteria

The criteria against which the Agency's activities were assessed, are:

1. Does the Canadian Food Inspection Agency have comprehensive and adequate inspection programs to ensure if aquaculture products are safe?

    1.1 Does the Canadian Food Inspection Agency prepare and implement comprehensive working plans that ensure that frequency of established controls for aquaculture products (inspections, sampling and audits) are determined in accordance with the level of food safety risks?

    1.2 Does the Canadian Food Inspection Agency investigate and take action on potential health hazards associated with aquaculture products brought to its attention through consumer complaints, import alerts, reports of illegal use of therapeutants, spills near aquaculture sites, etc.?

    1.3 Does the Canadian Food Inspection Agency utilize recognized analytical methodologies?

    1.4 Does the Canadian Food Inspection Agency request a Health Risk Assessment from Health Canada when analytical results of aquaculture products indicate a potential risk and Health Canada standards do not exist?

    1.5 Does the Canadian Food Inspection Agency implement its Service Standards that are applicable to the safety of aquaculture products?

2. Does the Canadian Food Inspection Agency ensure that risk management and controls for feeds in the areas related to aquaculture products are comprehensive and adequate?

    2.1 Does the Canadian Food Inspection Agency ensure that *Regulations of the Feeds Act* are adequate to ensure that manufactured feeds will not compromise the safety of aquaculture products?

    2.2 Does the Canadian Food Inspection Agency prepare and implement complete and comprehensive working plans for its inspections, sampling and audits of manufactured feeds based on reliable information on food safety risks associated with feeds used for aquaculture?

3. Are the respective roles and responsibilities for aquaculture clearly defined and understood?

   3.1 Does the CFIA make reasonable efforts to have agreements with other levels of government, other federal departments or other countries when such agreements would be potentially beneficial and contribute to reduce the gaps and duplication that could lead to the production of unsafe aquaculture products?

   3.2 Does the Canadian Food Inspection Agency ensure that it obtains valid and reliable information from its provincial, federal and industry partners in order to determine if the respective roles and responsibilities regarding aquaculture products are properly fulfilled?

   3.3 Does the Canadian Food Inspection Agency ensure that corrective actions are taken when MOUs and/or agreements with its provincial, federal and industry partners are not properly implemented?

   3.4 Does the Canadian Food Inspection Agency ensure cooperation and information sharing within its various divisions and sections having responsibilities for aquaculture products?

Scope and Approach

We examined CFIA activities related to the safety of domestic and imported aquaculture products between April 1, 1997 to March 31, 2000. More specifically, we examined inspection, laboratory and policy development activities relating to domestic and imported aquaculture products. We analysed situations of potential problems and situations of non-compliance consisting of illness reports, recalls, microbiological pathogens, chemical residues, and consumer complaints. We also examined the Agency inspection, laboratory and regulatory activities of the feed program related to aquaculture products. As aquaculture is clearly an area of shared jurisdictions, the roles and responsibilities of the various partners involved were also examined.

This assessment was undertaken according to the mandate defined in the Act establishing the Canadian Food Inspection Agency. In section 11 (4) of this Act it is specified that: "The Minister of Health is responsible for establishing policies and standards relating to the safety and nutritional quality of food sold in Canada and assessing the effectiveness of the Agency's activities related to food safety". Therefore the assessment role of the Minister of Health, as defined in this Act covers exclusively the CFIA and does not include the assessment of any activities related to food safety undertaken by Health Canada or any other federal or provincial organizations. Our scope reflects this legislative provision.

Assessment team:

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List of Acronyms

AMRL (Administrative Maximum Residue Limit)

AOAC (Association of Official Analytical Chemists)

CFIA (Canadian Food Inspection Agency)

CMIB (Compendium of Medicated Ingredients Brochure)

CSSP (Canadian Shellfish Sanitation Program)

DFO (Department of Fisheries and Oceans)

FAO (Food and Agriculture Organization of the United Nations)

FAPAS (Food Analysis Performance Assessment Scheme)

FDA (*Food and Drugs Act*)

FIA (*Fish Inspection Act*)

HACCP (Hazard Analysis Critical Control Points)

HRA (Health Risk Assessment)

ICTUA (Interdepartmental Committee on Therapeutant Use in Aquaculture)

MOU (Memorandum Of Understanding)

MRA (Mutual Recognition Agreement)

MRL (Maximum Residue Limit)

OAG (Office of the Auditor General)

OFSR (Office of Food Safety and Recall)

PCPA (*Pest Control Products Act*)

PMRA (Pest Management Regulatory Agency)

QMP (Quality Management Program)

US FDA (United States Food and Drugs Administration)

VDP (Veterinary Drug Program)